TESTIMONY OF

RONALD W. DOLLENS
PRESIDENT AND CHIEF EXECUTIVE OFFICER
GUIDANT CORPORATION
AND
MEMBER, BOARD OF DIRECTORS
HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

HEARING ON

PRODUCT LIABILITY REFORM

IN THE

SUBCOMMITTEE ON
TELECOMMUNICATIONS, TRADE AND CONSUMER PROTECTION
COMMITTEE ON COMMERCE
U.S. HOUSE OF REPRESENTATIVES

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My name is Ronald Dollens. I am President and Chief Executive Officer of Guidant Corporation. I serve as a member of the Health Industry Manufacturers Association (HIMA) Board of Directors and chair that organization's Biomaterials Subcommittee.

Guidant Corporation, headquartered in Indianapolis, Indiana, designs, manufactures and sells innovative products and technologies that improve the quality of healthcare for persons with cardiovascular diseases. Guidant's devices are manufactured in Minnesota, California, Puerto Rico, and Basingstoke, England.

The Health Industry Manufacturers Association is the largest medical technology association in the world, representing more than 700 manufacturers of medical devices, diagnostic products and medical information systems. HIMA is headquartered in Washington D.C. Its members manufacture nearly 90 percent of the more than $51 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $120 billion purchased around the world each year.

My testimony today will represent the views of not only my own company but also HIMA and its members.

INTRODUCTION

The member companies of HIMA strongly advocate the prompt enactment of meaningful federal product liability and biomaterials supplier liability reform legislation.

Inequities in the current U.S. product liability system severely threaten the ability of HIMA members, and other medical technology firms, to continue to provide innovative devices and therapies to U.S. patients. America's medical device companies are innovative. They invest an average of almost 7 percent of sales in research and development, nearly double the national average for manufacturing companies. This investment enhances the quality and value of patient care and raises the standard of health care in the United States. Unfortunately, our legal system has become the enemy of device industry innovation and, therefore, patient well-being. Within this industry there are many small, entrepreneurial companies, employing fewer than 100 workers. It is from these companies that the vast majority of dramatic innovations come. The current U.S. product liability system particularly endangers the future of these firms.

The U.S. device industry operates in an increasingly litigious environment. Today, because of the fear of lawsuits, companies in all industries decide not to pursue or support innovative ideas. In the medical device industry, as well as in many others, the challenges and opportunities associated with developing new technologies are not worth the potential product liability risk.

Many parties pay the price for the chaos created by our legal system. This testimony will focus on the cost to U.S. patients who may have to wait too long for, or never get, new life-saving or life-enhancing devices; to companies which are forced to fund litigation defenses instead of research and development efforts; and to our nation which must face the possibility of losing it's long-standing leadership in medical technology, and absorb the costs incurred within our healthcare delivery system.

Balanced federal product liability reform, in which the rights of all parties are clearly defined and responsibility for safety is placed with those best able to address it, is needed if device companies are to continue to enhance the health and well-being of the American people in a timely manner. HIMA has long supported key reforms in the area of product liability law, including the establishment of clear standards for awarding punitive damages; the elimination of joint liability for non-economic loss; and, perhaps most important, the enactment of procedures that will help manufacturers obtain continued

access to the raw materials and component parts essential to the manufacture of medical devices. The destructive impact of current liability laws on the medical device industry and the patients it serves is especially profound in this last area. As Senator Joe Lieberman has accurately stated, biomaterials access is a "public health time-bomb."

THE ISSUE

Each year, the lives of more than 7.5 million Americans are saved or substantially enhanced by implantable medical devices ranging from pacemakers to heart valves to hip and knee joints. However, our current legal system is threatening the ability of implantable device manufacturers to continue to provide these and other needed products.

Under today's product liability law, suppliers of the raw materials and components parts used in these life-saving and life-enhancing devices can be brought into product litigation against the device manufacturer, even though these suppliers have no involvement in the design, manufacture or sale of the device. Because some of our highest quality suppliers are large companies with considerable financial resources, they have come to be viewed by plaintiffs' counsel as "deep pockets." In no instance, in any court in this nation, has a supplier been found to be at fault in a device case that has gone to final judgment. Nonetheless, costs associated with defending themselves in litigation are forcing

suppliers out of the medical device market, which offers minimal profits but poses significant risk. Since 1992, 14 suppliers of essential biomaterials have withdrawn from the market. Patient access to needed products is being jeopardized and there is no reason to believe that this trend will reverse itself unless there is action by our government.

We do not fault the suppliers. Sound business practice requires that they take such action. Just look at the numbers. In 1994, implant manufacturers purchased $3,300 of polyacetal resin, while sales to all other markets totaled $1.3 billion. Polyester yarn sales to the device industry total $185,000 per year, while sales to all other markets total $9 billion per year. DuPont spent $8 million per year for five years defending, and winning, 259 cases arising from the use of Teflon@ in a temporo mandibular joint implant. Revenues derived from the sales of these materials to the device industry are simply too insignificant to justify the potential product liability risk.

If suppliers are forced to continue to leave the device market, the effect on American patients will be devastating. The range of biomaterials already restricted for sale to the device industry is broad. The entire spectrum of medical specialties, from cardiology to neurology to urology and ophthalmology, is impacted. To understand the magnitude of

this issue, the products which are currently affected by restrictions on the sale of biomaterials, or which are likely to be affected by such restrictions in the near future, must be considered:

Heart valves, used to control the flow of blood to and from the heart and between chambers of the heart. Some 35,000 patients receive heart valves annually.

Vascular grafts, used to repair or replace arteries in people whose own arteries have been injured or are in danger of catastrophic failure. Approximately 300,000 patients benefit from vascular grafts annually.

Pacemakers and defibrillators used to regulate heart beats which are too fast or too slow. More than 140,000 pacemakers and 35,000 defibrillators are implanted annually.

Intraocular lenses and related technologies used in cataract surgery. Some 1.5 million patients annually are affected by these products.

Hydrocephalus shunts, used to drain the buildup of cerebrospinal fluid from the brains of affected infants and children. About 75,000 shunts are implanted annually.

Arthroplasty devices -- such as artificial toe and finger joints, and hip and knee joints -- used to help 600,000 patients per year.

Catheters, used in about a million patients annually.

And this is just for now. Other products that could be significantly affected by the restrictions on the sale of biomaterials include: sutures, IV drip systems, implantable infusion pumps, wound drainage sets, wrist joint replacements, ostomy systems, and any number of grafts.

While the patients will pay the most obvious and compelling price, there are other costs associated with restrictions on the sale of biomaterials.

Today, device manufacturers must regularly divert R&D resources to a search for substitute materials. If located, these substitute materials are subjected to time consuming and costly testing by the company, and then the device is re-evaluated by regulators, to ensure that it meets safety standards. Also, manufacturers commonly provide costly indemnifications to existing suppliers, and pay exorbitant prices for needed materials. Large companies, in some cases, are willing and able to do this although the cost is great. Small companies cannot, and simply leave the industry. Jobs are lost; innovation suffers; American patients lose.

Further, the competitiveness of the U.S. medical device industry is threatened because companies must focus on this search for new materials and component parts rather than on R&D for new products. If the U.S. loses it's leadership, it will be to the detriment of many, but especially our patients.

Opponents of this legislation have charged that there is no shortage. Physician specialty groups, such as the American College of Cardiology and the Society of Thoracic Surgeons; consumer and patients groups including the Center for Patient Advocacy and the Paralyzed Veterans of America; national health organizations such as the Society for

the Advancement of Women's Health Research; and U.S. manufacturers who have had to find new suppliers or provide costly indemnification and insurance policies to ensure a continued supply of materials, strongly disagree. These are the people who see the problem daily. This is not a theoretical "what if' situation. Evidence exists of shortages. The 1997 Aronoff Associates study and the 1995 Wilkerson study both validate the problem.

THE SOLUTION

The biomaterials shortage can be addressed effectively if Congress will pass and the President will sign product liability reform legislation that includes HR 872, the "Biomaterials Access Assurance Act of 1997."

Congress has considered legislative solutions to the biomaterials access problem since 1994. Support for reform on Capitol Hill, within the healthcare community and among the public has increased as there has developed a greater understanding of the public health implications of the biomaterials shortage. In 1996, biomaterials access assurance legislation passed both houses of Congress as a part of HR 956, the "Common Sense Product Liability Legal Reform Act of 1996." Unfortunately, President Clinton vetoed this legislation.

The biomaterials access assurance legislation before this Committee has been carefully crafted to address the needs of patients, materials suppliers and device manufacturers. It is quite simple. It would allow biomaterials suppliers to be dismissed, without extensive discovery and legal costs, from product liability suits in which they are named, if their only connection with the alleged injury is supplying a biomaterial that fully meets all contractual specifications. This is fair. It puts responsibility for the product squarely on the manufacturer who designs and produces it.

The bill does not allow suppliers who furnish products that fail to meet contract specifications to be dismissed from litigation brought by a person alleging injury. It does not allow for dismissal of suppliers who are themselves manufacturers or sellers of the products. Actions may proceed against suppliers who are wrongdoers or are in a position to control the manufacture or sale of an implantable device.

Also, to address concerns expressed by some regarding the affect of legislation on silicone gel breast implant litigants, HIMA supports excluding from the bill claimants alleging harms caused by the silicone gel or the silicone envelope used in a breast implants.

Because the proposed biomaterials reforms are prospective and not retroactive, we do not agree with assertions that the legislation would affect the ability of current breast implant litigants to seek compensation from silicone gel suppliers for alleged harm caused by silicone gel breast implants. More important, a U.S. federal court in Oregon recently ruled that many of the studies relied upon by breast implant plaintiffs are, in effect, no more than "junk science" and should be excluded from evidence because they fail to establish the probability that silicone gel breast implants cause disease. Nevertheless, in order to help assure enactment of biomaterials legislation that will preserve continued access to the life-saving, life-enhancing implantable medical devices used by more than 7.5 million patients annually, HIMA reluctantly agreed to the silicone gel breast implant carveout.

The biomaterials access reforms advocated would not in any way diminish the liability of medical device manufacturers. Persons alleging injury would retain their rights to sue the manufacturer of the device. Device manufacturers willingly accept this responsibility. However, to help ensure the continued availability of the biomaterials they need to make the products American patients require, they advocate that those suppliers not responsible for the design, manufacture or sale of the product be excluded from litigation unless there is evidence of wrongdoing. Device manufacturers qualify materials and undergo a

rigorous approval process at the FDA to demonstrate the safety and efficacy of their products. Only they have the competence to determine whether the materials and component parts they purchase are safe when implanted in the human body and they accept the responsibility for making such decisions.

Biomaterials access reform will not diminish the ability of injured persons to seek redress against appropriate parties for harm alleged to have been caused by a medical implant. It will, however, help to ensure that U.S. patients continue to have access to the medical devices they need, and it will prevent a potentially greater harm -- the disappearance of many life-saving, life-enhancing devices from our medical arsenal.

I appreciate the interest of the Committee in this important public health matter, and look forward to assisting in efforts to enact meaningful reforms that will help to ensure that U.S. patients have continued access to life-saving and life-enhancing medical devices.

Thank you for your attention.

Summary of Testimony by
Ronald W. Dollens
President and Chief Executive Officer
Guidant Corporation
and
Member, Board of Directors
Health Industry Manufacturers Association

- The United States legal system has become the enemy of device industry innovation and, thereby, patient well-being.

- Device industry innovation and patient well-being are threatened because suppliers of materials and component parts used in implantable medical devices are withdrawing from the market. Suppliers are taking this action because, although having no role in the design, manufacture or sale of a device, they, nevertheless, become the "deep pocket" in litigation alleging a device defect. While eventually dismissed from the action, revenues derived from sales to the medical device industry cannot justify the significant legal costs incurred by suppliers.

- If suppliers continue to exit the medical device market, the impact on American patients will be devastating. Already, the entire spectrum of medical specialties, including cardiology, neurology, urology and ophthalmology, is being affected. Life-saving and life-enhancing devices, such as pacemakers, heart valves, vascular grafts, hydrocephalus shunts, catheters, intraocular lenses, and hip joints, could be endangered.

- Device manufacturers have already been forced to divert resources from research and development on new therapies to a search for alternate materials. To secure needed materials and component parts, manufacturers must pay ever escalating prices and enter into costly indemnification agreements. The situation is particularly difficult for smaller entrepreneurial companies, from which much dramatic innovation comes.

. To remedy this situation, the U.S. medical device industry advocates limiting the liability of materials and components parts suppliers to instances of genuine fault, and establishing procedures to ensure that such suppliers can be dismissed from litigation prior to incurring substantial legal expenses.

. These reforms ***would not*** relieve medical device manufacturers of their liability. The reforms *would not* prevent persons alleging injury caused by a device from seeking redress from responsible parties. These reforms *would* help to ensure that U.S. patients continue to have access to life-saving and life-enhancing medical therapies.

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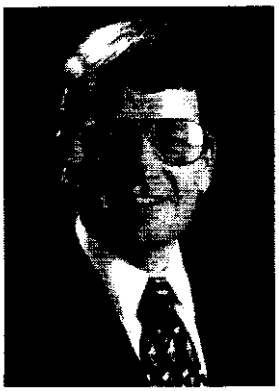
GUIDANT

RONALD W. DOLLENS



NAME: Ronald W. Dollens

TITLE: President and CEO, Guidant Corporation

LOCATION: Indianapolis

TELEPHONE: (317) 971-2000

Ronald W. Dollens is president and chief executive officer of Guidant Corporation, a $1 billion company traded on the New York and Pacific stock exchanges (NYSE and PSE:GDT).

Mr. Dollens has 25 years experience in the health care industry. Prior to the formation of Guidant Corporation, he served as president of Eli Lilly and Company's Medical Devices and Diagnostics Division (MDD). Prior to that, he was vice president of MDD, and president of the Vascular Intervention Group.

Mr. Dollens joined Lilly in 1972 as a pharmaceutical sales representative in Toledo, Ohio. He also served the Rochester, New York, territory before being transferred to the company's headquarters in 1976. Two years later, he was named manager of economic studies and, in 1981, became manager of the Los Angeles north sales district. He was named director of business development for MDD in November 1982. In April 1985, Ron became the senior vice president of sales, marketing, research and development for Advanced Cardiovascular Systems (ACS) headquartered in Santa Clara, California. In 1988, he became ACS' president and chief executive officer.

Ron received a Bachelor of Science degree in pharmacy from Purdue University in 1970, and a Master of Business Administration degree in marketing from Indiana University in 1972.

Mr. Dollens currently serves on the board of the Health Industry Manufacturers Association, Eiteljorg Museum Board, and the Indiana State Symphony Society Board. He is also the president of the Indiana Health Industry Forum.

GUIDANT CORPORATION
111 Monument Circle Tower, Suite 2900
Indianapolis, Indiana 46204-5129
317/971-2000 FAX 317/971-2192